

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS USA, INC.,  
TEVA PHARMACEUTICAL  
INDUSTRIES LTD., TEVA  
NEUROSCIENCE, INC., and YEDA  
RESEARCH AND DEVELOPMENT CO.,  
LTD.,

Plaintiffs,

v.

DOCTOR REDDY'S LABORATORIES,  
LTD., DOCTOR REDDY'S  
LABORATORIES, INC., SANDOZ INC.,  
MOMENTA PHARMACEUTICALS,  
INC., MYLAN PHARMACEUTICALS  
INC., MYLAN INC., SYNTHON  
PHARMACEUTICALS INC., SYNTHON  
B.V., SYNTHON S.R.O., PFIZER INC.,  
AMNEAL PHARMACEUTICALS LLC,  
AMNEAL GMBH, BIOCON LTD., and  
APOTEX CORP.,

Defendants.

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AMNEAL PHARMACEUTICALS LLC and  
AMNEAL PHARMACEUTICALS COMPANY  
GMBH,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.,  
TEVA PHARMACEUTICAL INDUSTRIES,  
LTD., and TEVA NEUROSCIENCE, INC.,

Defendants.

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C.A. No. 16-1267-GMS

C.A. No. 17-074-GMS

MOMENTA PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 17-109-GMS
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
TEVA PHARMACEUTICAL INDUSTRIES,	)	
LTD., and TEVA NEUROSCIENCE, INC.,	)	
	)	
Defendants.	)	
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	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
TEVA PHARMACEUTICAL INDUSTRIES	)	
LTD., and TEVA NEUROSCIENCE, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 17-249-GMS
	)	
MYLAN PHARMACEUTICALS INC. and	)	
MYLAN INC.,	)	
	)	
Defendants.	)	
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	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
TEVA PHARMACEUTICAL INDUSTRIES	)	
LTD., and TEVA NEUROSCIENCE, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 17-390-GMS
	)	
SYNTHON PHARMACEUTICALS INC.,	)	
SYNTHON B.V., SYNTHON S.R.O., and	)	
PFIZER INC.,	)	
	)	
Defendants.	)	

**JOINT STATUS REPORT**

Pursuant to Fed. R. Civ. P. 16, D. Del. LR 16.1, and the Court's Oral Order of May 16, 2017, the parties, by and through their undersigned counsel, submit this single, jointly prepared Joint Status Report covering the following cases, each of which involves U.S. Patent No. 9,155,775, entitled "Process for Manufacturing Glatiramer Acetate Product" ("the '775 patent"): C.A. Nos. 16-cv-1267-GMS, 17-cv-74-GMS, 17-cv-109-GMS, 17-cv-249-GMS, and 17-cv-390-GMS, 17-cv-00597-GMS (collectively, the "'775 Patent Cases"). Counsel for the parties participated in telephonic conferences pursuant to the Notices of Scheduling Conferences and as required by Fed. R. Civ. P. 26(f) on various dates, including March 17, 2017, and subsequent dates. The following participated in telephone conferences:

- Shaw Keller LLP and Goodwin Procter LLP participated on behalf of Plaintiffs Teva Pharmaceuticals USA, Inc. ("Teva USA"), Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), Teva Neuroscience, Inc. ("Teva Neuroscience") (collectively, "Teva" or "Plaintiffs");
- Phillips, Goldman, McLaughlin & Hall, P.A. and Budd Lerner, P.C. participated on behalf of Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL");
- Heyman, Enerio, Gattuso & Hirzel LLP and Rakoczy Molino Mazzochi Siwik LLP participated on behalf of Defendants Sandoz Inc. ("Sandoz") and Momenta Pharmaceuticals, Inc. ("Momenta");
- Richards Layton & Finger, P.A. and Perkins Coie LLP participated on behalf of Defendants Mylan Inc., Mylan Pharmaceuticals Inc. (collectively, "Mylan") and Natco Pharma Ltd. ("Natco");
- Smith, Katzenstein & Jenkins LLP and Rothwell, Figg, Ernst & Manbeck, P.C. participated on behalf of Defendants Synthon Pharmaceuticals Inc., Synthon B.V., Synthon s.r.o., and Pfizer Inc. (collectively, "Synthon"); and
- Duane Morris LLP participated on behalf of Defendants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals Company GmbH (collectively, "Amneal").

The parties attach, for the Court's consideration, a chart summarizing the parties' scheduling proposals for this action (Exhibit A).

The six '775 Patent Cases pending in this Court are listed here for the Court's convenience:

1. *Teva Pharm. USA, Inc. et al. v. Doctor Reddy's Labs., Ltd. et al.*, Case No. 16-cv-01267-GMS (D. Del.) (Declaratory Judgment counterclaims by Sandoz/Momenta, DRL, Mylan and Synthon/Pfizer).
2. *Teva Pharm. USA, Inc. et al. v. Mylan Pharm. Inc. et al.*, Case No. 17-cv-00249-GMS (D. Del.) (previously Case No. 17-cv-00007-IMK (N.D. W. Va.));
3. *Teva Pharm. USA, Inc. et al. v. Synthon Pharm. Inc. et al.*, Case No. 17-cv-00390-GMS (previously Case No. 17-cv-00345-LGS (S.D.N.Y.));
4. *Teva Pharm. USA, Inc. et al. v. Sandoz Inc.*, Case No. 17-cv-547-GMS (D. Del.) (previously Case No. 17-275(FLW) (D.N.J.));
5. *Momenta Pharm., Inc. v. Teva Pharm. USA, Inc. et al.*, Case No. 17-cv-00109-GMS (D. Del.) (Declaratory Judgment Action); and
6. *Amneal Pharm. LLC et al. v. Teva Pharm. USA, Inc. et al.*, Case No. 17-cv-00074-GMS (D. Del.) (Declaratory Judgment Action).

Teva believes that all of the cases regarding the '775 patent should be consolidated for all purposes. In view of the recent decisions granting Defendants' motions to transfer a number of the above-referenced actions to this Court, Teva proposes that it will withdraw its motion to dismiss and/or stay or transfer the counterclaims directed to the '775 patent in C.A. No. 16-cv-01267-GMS; its motion to transfer C.A. No. 17-cv-74-GMS; its motion to stay C.A. No. 17-cv-109; and its objection to the motion to transfer of C.A. No. 17-cv-517 against DRL involving the '775 patent from the District of New Jersey to this District; and that it will not object to transferring C.A. No. 1:17-cv-416-JAM-AYS to this District from the Eastern District of New York. All of these actions concern the same patent, and in Teva's actions asserting the '775 patent, the Defendants have asserted counterclaims of invalidity and non-infringement of the '775 patent that are identical to the counterclaims in C.A. No. 16-cv-1267-GMS. Defendants have previously argued that these cases should be consolidated, and now that the venue issues

have been resolved with all of the cases proceeding in this District, Teva believes that these cases should be consolidated for all purposes, including trial. Having argued in this Court, and having successfully argued to other courts in the context of their motions that transfer to this Court would avoid the risk of inconsistent results from separate proceedings involving the same patent, Defendants should not be permitted to argue against consolidation for all purposes, including trial. Moreover, with the exception of Amneal's claims, Defendants' counterclaims of declaratory judgment of non-infringement and invalidity were all raised in the same action, C.A. No. 16-cv-1267-GMS, and as a result, will all be tried together. Consolidation for trial of the other actions involving the same patent and same counterclaims makes sense from a judicial efficiency perspective and will avoid the need for multiple trials, and potentially multiple jury trials, on the same issues.

Defendants/Declaratory Judgment Plaintiffs (hereinafter, "Defendants")<sup>1</sup> agree that the '775 Patent Cases should be consolidated, at least for all pretrial proceedings, with Case No. 16-cv-1267-GMS being designated the lead case. Defendants submit that consolidation of all cases for trial is premature, particularly since such consolidation is impermissible without all Defendants' consent under 35 U.S.C. § 299(a)(1). Teva is simply wrong in asserting that "Defendants' counterclaims of declaratory judgment of non-infringement and invalidity were all raised in the same action, C.A. No. 16-cv-1267-GMS," because Amneal did not assert any counterclaims in that case concerning the '775 patent. Furthermore, in their briefing on the transfer issue in both the transferor court and this Court, Defendants consistently argued that consolidation would conserve party and judicial resources. No Defendant, however, argued

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<sup>1</sup> Defendants in the '775 Patent Cases are Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals Co. GmbH; Dr. Reddy's Laboratories, Ltd., and Dr. Reddy's Laboratories, Inc.; Mylan Pharmaceuticals Inc., and Mylan Inc.; Sandoz Inc. and Momenta Pharmaceuticals, Inc.; and Synthon Pharmaceuticals Inc., Synthon B.V., Synthon s.r.o., and Pfizer Inc.

that consolidation *for trial* was appropriate—and indeed, could not have done so unless and until all defendants agreed to consolidation for trial after the cases were transferred—and no Defendant waived its right under 35 U.S.C. § 299 for a separate trial. That statutory provision bars consolidation for trial in this circumstance because Plaintiffs’ right to relief does not arise out of “the same transaction, occurrence, or series of transactions or occurrences relating to the making, using, importing into the United States, offering for sale, or selling of the same accused product or process.” Defendants do not use the same accused process, and as a result, there will be issues relating to non-infringement that are unique for each Defendant. Similarly, issues relating to damages will be unique to each Defendant. In fact, whether or not Teva is entitled to a jury trial may be different for different Defendant groups. However, Defendants agree that the interests of justice and the convenience of the parties unequivocally support pretrial consolidation of all of the ’775 Patent Cases in Delaware. Indeed, pretrial consolidation of the six cases currently pending in this Court will be more efficient and less costly for the parties, and more convenient and efficient for the Court. Pretrial consolidation of all of Plaintiffs’ ’775 patent infringement claims in Delaware will also avoid the risk of inconsistent results on issues like claim construction and invalidity, and will be less burdensome on the federal judicial system than requiring multiple concurrent proceedings in different forums. Defendants therefore ask that the cases be consolidated for pretrial purposes and the decision on whether or not to consolidate one or more of the cases for trial be deferred until a later date when the issues to be tried become clearer through fact and expert discovery.

## **1. Jurisdiction and Service**

These patent infringement suits arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). This Court has subject matter jurisdiction over the declaratory judgment actions

pursuant to 28 U.S.C. §§ 2201 and 2202, 1331 and 1338(a). All Defendants have been served with process and have agreed not to contest jurisdiction and venue in this Court for purposes of these actions.

## **2. Substance of Action**

### ***Case No. 16-cv-1267-GMS***

Case No. 16-cv-1267-GMS was brought by Plaintiffs for alleged infringement of United States Patent No. 9,402,874 entitled “Low Frequency Glatiramer Acetate Therapy” (“the ’874 patent”), which is directed to methods of treatment. Defendants Mylan, Sandoz, Momenta, Synthon, and DRL have filed counterclaims in Case No. 16-cv-1267-GMS seeking declaratory judgments of noninfringement and invalidity of the ’775 patent, which is owned by Plaintiff Teva Ltd. and entitled “Process for Manufacturing Glatiramer Acetate Product.” As a process patent, the ’775 patent is not eligible for listing in the Orange Book.<sup>2</sup> On April 23, the parties stipulated to a dismissal with prejudice of the ’874 claims and counterclaims subject to the terms set forth in the parties’ Joint Stipulation and [Proposed] Order Dismissing with Prejudice Claims and Counterclaims Regarding U.S. Patent No. 9,402,874 (D.I. 72). The Court signed the Stipulated Dismissal of the ’874 claims and counterclaims on May 1, 2017 (D.I. 74).

The ’775 patent counterclaims of Defendants Mylan, Sandoz, Momenta, Synthon, and DRL remain pending. On January 25, 2017, Amneal filed a declaratory judgment action concerning the ’775 patent in this District. *Amneal Pharmaceuticals LLC, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, C.A. No. 17-cv-74-GMS. Amneal’s declaratory judgment action was the first action in Delaware in which the ’775 patent was put at issue. Prior to Defendants Mylan, Sandoz, Momenta, Synthon, and DRL asserting their ’775 patent declaratory judgment counterclaims in C.A. No. 16-cv-01267-GMS, in January 2017, Teva filed Complaints

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<sup>2</sup> Accordingly, the ’775 Patent Cases are not Hatch-Waxman cases.

asserting the '775 patent against Defendants Sandoz/Momenta, DRL, Mylan, Synthon, and Amneal, in other jurisdictions: the District of New Jersey (Sandoz/Momenta and DRL), the Southern District of New York (Synthon), the Eastern District of New York (Amneal)<sup>3</sup>, and the Northern District of West Virginia (Mylan). On March 9, 2017, Plaintiffs filed a motion to dismiss and/or stay or transfer the counterclaims directed to the '775 patent in Case No. 16-cv-1267-GMS (D.I. 56). Defendants Mylan, Sandoz, Momenta, Synthon, and DRL filed a combined brief opposing Plaintiffs' motion on March 23, 2017. On March 30, Plaintiffs filed a reply brief in support of its motion to dismiss and/or stay or transfer the counterclaims directed to the '775 patent in this case. That motion is now fully briefed. Plaintiffs and Defendants now agree that, given the critical mass of cases and claims on the '775 patent that will be proceeding in this Court, consolidated proceedings in Delaware, with Case No. 16-cv-1267-GMS being designated the lead case, will promote efficiency and convenience, conserve judicial resources, and avoid the risk of inconsistent results. As set forth above, Plaintiffs propose that the cases should be consolidated for all purposes and that Plaintiffs will withdraw their motions to dismiss and/or stay or transfer the counterclaims directed to the '775 patent in Case No. 16-cv-1267-GMS. Defendants propose that the case should be consolidated for pretrial purposes only, and that Plaintiffs should immediately withdraw their motions to dismiss and/or stay or transfer the counterclaims directed to the '775 patent in Case No. 16-cv-1267-GMS.

***The Transferred Cases: Case Nos. 17-cv-249-GMS, 17-cv-00390-GMS and 17-cv-547-GMS***

In January 2017, Plaintiffs Teva Ltd., Teva USA, and Teva Neuroscience filed Complaints asserting the '775 patent against Defendants Sandoz/Momenta, DRL, Mylan, and

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<sup>3</sup> Teva's suit against Amneal in the Eastern District of New York was filed after Amneal filed its declaratory judgment action concerning the '775 patent in this District.

Synthon in other jurisdictions: the District of New Jersey (Sandoz/Momenta and DRL), the Southern District of New York (Synthon), and the Northern District of West Virginia (Mylan).

On March 10, 2017, the Northern District of West Virginia transferred the suit Plaintiffs filed against Mylan on the '775 patent to this Court. *See Teva Pharms. USA, Inc. v. Mylan Pharms. Inc.*, 17-cv-00249 (D. Del.). On May 4, 2017, Mylan answered and asserted counterclaims of invalidity and noninfringement of the '775 patent. Natco moved to dismiss the claims pursuant to Rule 12(b)(6). On May 26, 2017, the parties stipulated to a dismissal of the claims against Natco subject to the terms set forth in the Stipulation of Dismissal of Defendant Natco Pharma Ltd. and Proposed Order Updating Case Caption (D.I. 73). The Court signed the Stipulated Dismissal of the claims against Natco on May 30, 2017 (D.I. 73).

On March 31, 2017, the Southern District of New York transferred the suit Plaintiffs filed against Synthon Pharmaceuticals Inc., Synthon B.V., Synthon s.r.o., and Pfizer Inc. on the '775 patent to this Court. *See Teva Pharm. USA, Inc. et al. v. Synthon Pharm. Inc. et al*, Case No. 17-cv-00390-GMS (D. Del.). On April 17, 2017, Synthon answered and asserted counterclaims of invalidity and noninfringement of the '775 patent. Teva answered Synthon's counterclaims on May 8, 2017.

On May 23, 2017, the District of New Jersey transferred the suit against Sandoz Inc. to this Court. *See Teva Pharm. USA, Inc. et al. v. Sandoz Inc.*, C.A. No. 17-275(FLW), Dkt. No. 90 (D.N.J.).<sup>4</sup> On June 1, 2017, the District of New Jersey transferred the suit against DRL to this

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<sup>4</sup> On January 13, 2017, Plaintiffs Teva Ltd., Teva USA, and Teva Neuroscience filed a Complaint asserting the '775 patent against both Sandoz and Momenta in the District of New Jersey (C.A. No. 17-275-FLW). On January 25, 2017, Momenta moved to dismiss for lack of personal jurisdiction in New Jersey, and Sandoz and Momenta jointly moved to transfer the case to Delaware. (C.A. No. 17-275-FLW D.I. 9, 7). On January 31, 2017, Plaintiffs in that case dismissed Momenta from C.A. No. 17-275-FLW without prejudice. As such, Sandoz was the only defendant at the time the case was transferred.

Court. *See Teva Pharm. USA, Inc. et al. v. Dr. Reddy's Labs., Ltd.*, C.A. No. 17-517 (FLW), Dkt. No. 41 (D.N.J.)

***The Declaratory Judgment Actions: Case Nos. 17-cv-74-GMS and 17-cv-109-GMS***

On January 25, 2017, Amneal filed the first action concerning the '775 patent in this District seeking a declaration of, *inter alia*, noninfringement and patent invalidity. *Amneal Pharmaceuticals LLC, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, C.A. No. 17-cv-74-GMS. Later that same day, Teva Ltd., Teva USA and Teva Neuroscience filed suit against Amneal in the Eastern District of New York, alleging infringement of the '775 patent. *Teva Pharmaceuticals USA, Inc., et al. v. Amneal Pharmaceuticals LLC, et al.*, C.A. No. 1:17-cv-416-JAM-AYS (E.D.N.Y.). On February 27, 2017, Amneal moved this Court to enjoin Teva from proceeding with parallel litigation in the Eastern District of New York. On March 7, 2017, Teva moved this Court to transfer Amneal's '775 patent declaratory judgment case from Delaware to the Eastern District of New York. (C.A. No. 17-cv-74-GMS D.I. 30). Both motions are fully briefed. The Eastern District of New York has stayed Teva's case there pending this Court's resolution of the venue issues in Amneal's motion to enjoin and Teva's motion to transfer. As set forth above, Teva proposes that the parties agree to transfer the action pending in the Eastern District of New York, C.A. No. 1:17-cv-416-JAM-AYS (E.D.N.Y.), to this District and be consolidated with these actions for all purposes, and that Teva withdraw its motion to transfer the action pending in this District, C.A. No. 17-cv-74-GMS. Amneal proposes that Teva's second-

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Also, on February 17, 2017, Teva moved for a preliminary injunction in New Jersey enjoining Sandoz from launching its generic GA 40 mg/mL product. (C.A. No. 17-275-FLW D.I. 51-52). On March 17, 2017, due to changed factual circumstances, specifically, a warning letter Sandoz's contract manufacturer for its generic 40 mg/mL product received from FDA on February 14 and that warning letter's probable impact on the approval of Sandoz's generic product, Teva asked the New Jersey Court to administratively terminate the Motion for Preliminary Injunction subject to reinstatement. (C.A. No. 17-275-FLW D.I. 69).

filed New York action, C.A. No. 1:17-cv-416-JAM-AYS (E.D.N.Y.), be transferred to this District and consolidated with Case No. 16-cv-1267-GMS for pretrial purposes only pursuant to 35 U.S.C. § 299.

On February 2, 2017, after Teva voluntarily dismissed Momenta without prejudice from its suit then pending in New Jersey on the '775 patent, Momenta filed a declaratory judgment action in this District over the '775 patent (C.A. No. 17-cv-109-GMS). Teva has answered the complaint and asserted counterclaims of infringement. As noted above, Teva proposes that it withdraw its motion to stay this action and that this action be consolidated with the other actions involving the '775 patent for all purposes, as set forth above. Defendants propose that the cases should be consolidated for all *pretrial* purposes at this time as discussed *supra*.

### ***Substance of Actions***

These are actions brought by Teva for infringement of the '775 patent or brought by defendants seeking declaratory judgment of noninfringement and invalidity with respect to the '775 patent. Defendants hold the following Abbreviated New Drug Applications seeking approval from FDA to market proposed generic glatiramer acetate 40 mg/mL products:

- DRL holds ANDA No. 206767
- Synthon holds ANDA No. 206873
- Sandoz holds ANDA No. 206921. Momenta developed the process for preparing Sandoz's glatiramer acetate 40 mg/mL ANDA product
- Mylan holds ANDA No. 206936. Natco supplies the active pharmaceutical ingredient used to make Mylan's glatiramer acetate 40 mg/mL ANDA product
- Amneal holds ANDA No. 207553

The same proposed generic products were at issue in a prior case, for which this Court held a seven-day bench trial in September and October 2016. *See In re Copaxone Consolidated Cases*, No. 14-cv-1171 (D. Del., filed Sep. 10, 2014) (the "Consolidated Delaware Action").

Unlike the patents at issue in the Consolidated Delaware Action, the '775 patent, which claims methods of manufacture, is not listable or listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as "the Orange Book" ("Orange Book"), with respect to Copaxone® 40 mg/mL injection. The '775 patent is directed to a process for preparing a pharmaceutical preparation of glatiramer acetate and mannitol.

### **3. Identification of the Issues**

The legal and factual issues in dispute in the '775 Patent Cases include at least the following: (a) the scope of the claims of the '775 patent; (b) whether Defendants infringe one or more claims of the '775 patent; and (c) whether the claims of the '775 patent are invalid and/or unenforceable. Additional issues include Teva's claims for damages, Teva's claims for injunctive relief, whether this case is exceptional pursuant to 35 U.S.C. § 285, and whether any party should be awarded its reasonable attorneys' fees, costs and disbursements. Additional issues raised include whether Sandoz and Momenta are permitted to use their pre-existing ANDA process conditions to prepare GA40 under the fair use provisions of 35 U.S.C. § 273.

### **4. Narrowing of Issues**

At this time, the parties have stipulated to a dismissal with prejudice of the '874 patent claims and counterclaims in Case No. 16-cv-1267-GMS, subject to the terms set forth in Joint Stipulation and [Proposed] Order Dismissing with Prejudice Claims and Counterclaims Regarding U.S. Patent No. 9,402,874 (D.I. 72, 74). Thus, the '874 patent is no longer involved in any case before this Court. The only patent in suit is the '775 patent. No remaining claims have been brought by or directed to Biocon Ltd. or Apotex Corp., both defendants in Case No. 16-cv-1267, or Yeda Research and Development Co., Ltd., a plaintiff in Case No. 14-cv-1171. These parties are therefore no longer involved in these cases.

## 5. Relief

Teva seeks judgment that the '775 patent is not invalid, is enforceable, and is infringed by each Defendant; judgment that the making, using, offering to sell, selling, marketing, distributing, or importing of Defendants' Glatiramer Acetate Products prior to the expiration of the '775 patent will infringe, actively induce infringement, and/or contribute to the infringement of one or more claims of the '775 patent; an Order preliminarily and permanently enjoining Defendants from commercially manufacturing, offering for sale, selling, or importing Defendants' Glatiramer Acetate Products until after the expiration of the '775 patent; damages or other monetary relief to compensate Teva to the extent Defendants have engaged or engage in the commercial manufacture, offer to sell, or importation into the United States of Defendants' Glatiramer Acetate Products, prior to the expiration of the '775 patent; judgment that this is an exceptional case and an award to Teva of its attorneys' fees under 35 U.S.C. § 285; judgment that Defendants' infringement of the '775 patent is willful; and an award of Teva's reasonable costs and expenses in this action. Teva requests that all actions before this Court concerning the '775 patent be consolidated for all purposes. Teva denies that Defendants are entitled to any relief on their claims relating to the '775 patent or that Sandoz and Momenta have a valid defense under 35 U.S.C. § 273. Should it succeed on the merits, Teva seeks any and all relief to which it would be entitled under law and equity for infringement of the '775 patent, including an injunction barring defendants from infringing that patent by practicing the claimed process in the United States or importing, offering for sale, selling and/or using in the United States any product made using that patented process. Teva disagrees with Defendants' assertion that the Court's prior decision concerning nexus to the dosing patents necessitates a finding that there is no nexus between the claims of the '775 patent and sales of Copaxone®, an issue never previously addressed by this Court.

Defendants request a judgment that the '775 patent is not infringed, is invalid, and is unenforceable. Defendants also submit that Plaintiffs would not be entitled to the broad relief requested, even if they were successful on the merits. As a threshold issue, the Court has already found no nexus exists between Teva's product sales and Teva's human dosing patents; *a fortiori*, nexus cannot exist between a claimed filtration method and product sales. Moreover, Plaintiffs' request for relief, including their request for an Order enjoining "Defendants from commercially manufacturing, offering for sale, selling, or importing Defendants' Glatiramer Acetate Products until after the expiration of the '775 patent," is overly broad and not justified. As the parties acknowledge, these cases are not Hatch-Waxman cases, because the claims of the '775 patent are directed to a discrete manufacturing step.<sup>5</sup> See *supra* Section 2. Thus, the '775 patent is not listed in the Orange Book and Defendants' ANDA submissions to the FDA were not required to, and did not, include certifications with respect to the '775 patent. Therefore, any judgment or order in this case would need to be narrowly tailored to the specific process step claimed in the '775 patent – namely the low-temperature filtration step. Even if Plaintiffs were to meet their additional burden of proving entitlement to injunctive relief, such relief would need to be narrowly tailored to prevent use of the claimed process and not broadly preclude manufacture, use, importation, sale or offer for sale of Defendants' glatiramer acetate products.

Relatedly, Defendants also submit that even if Plaintiffs were to meet their burden of proving infringement, Plaintiffs could not recover lost profits damages for several reasons, including that the accused filtration process is not the basis for demand for glatiramer acetate 40

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<sup>5</sup> Plaintiffs do not agree that the claims of the '775 patent are "directed to a discrete manufacturing step." The claims of the '775 patent are directed to processes for preparing a pharmaceutical preparation of glatiramer acetate and mannitol comprising certain steps, one of which is filtering the pharmaceutical solution.

mg/ml. Accordingly, even if Teva could establish entitlement to any relief at all, it would be no more than a reasonable royalty.

Sandoz and Momenta also request that this Court find and declare that Sandoz and Momenta are permitted to use their pre-existing ANDA process conditions to prepare GA40 under the fair use provisions of 35 U.S.C. § 273. Defendants further request an order decreeing that this case is exceptional, and that fees and costs incurred in this action be awarded to Defendants.

**6. Amendment of Pleadings**

The parties' proposed deadline for amendment to the pleadings is set forth in Exhibit A.

**7. Joinder of Parties**

The parties' proposed deadline for joinder of additional parties is set forth in Exhibit A.

**8. Discovery**

The parties anticipate that, if the case proceeds, discovery will be needed regarding the infringement, validity, and unenforceability of the '775 patent. The parties anticipate needing the following forms of discovery: (i) written discovery, including but not limited to requests for documents, requests for admission, and interrogatories; (ii) depositions of fact witnesses, including but not limited to deposition testimony pursuant to Federal Rule of Civil Procedure 30(b)(6); and (iii) expert discovery, including but not limited to expert reports and depositions.

(a) Given the number of Defendants and the possibility of individual disputes, the parties request an increase in the number of discovery dispute teleconferences with the Court to six (6), with any further teleconferences only upon a showing of good cause.

(b) The parties propose that they adhere to the limitations on discovery set forth in the Federal Rules of Civil Procedure, the Local Rules, and the Court's Default Standard for Discovery, except that:

- i. **Requests for Admission:** Plaintiffs shall be limited to forty (40) requests for each Defendant Group<sup>6</sup>, except for the purpose of authenticity. Each Defendant Group shall be limited to forty (40) requests for admission, except for the purpose of authenticity.
- ii. **Interrogatories:** Plaintiffs shall be permitted to serve twenty (20) interrogatories, including distinct and separate subparts, per each Defendant Group. Each Defendant Group shall be permitted to serve ten (10) interrogatories, including distinct and separate subparts, on Plaintiffs. Further, Defendants collectively shall be permitted to serve twenty (20) common interrogatories, including distinct and separate subparts.
- iii. **Fact Depositions:**

Number of depositions:

1. Plaintiffs shall be permitted to take five (5) fact depositions for each Defendant Group. Defendants collectively shall be permitted to take up to fifteen (15) fact depositions of Plaintiffs, inclusive of inventor depositions. Where multiple Defendant Groups seek to take the deposition of the same fact witness, the witness shall be offered only once, at a time agreeable to all parties. If additional depositions are needed, and if good cause is shown, the parties may take additional depositions upon agreement of the parties or by leave of court.

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<sup>6</sup> The Defendant Groups are (i) Mylan Pharmaceuticals Inc. and Mylan Inc.; (ii) Sandoz Inc. and Momenta Pharmaceuticals, Inc.; (iii) Synthon Pharmaceuticals Inc., Synthon B.V., Synthon s.r.o., and Pfizer Inc.; (iv) Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals Company GmbH; and (v) Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.

30(b)(6) depositions:

2. Seven hours of deposition testimony taken pursuant to Federal Rule of Civil Procedure 30(b)(6) shall count as a single deposition toward the deposition limit, no matter how many deposition topics are included in the notice, and no matter how many witnesses are assigned by a party to testify about the deposition topics. Any party may designate more than one person to testify pursuant to Rule 30(b)(6). Each day of deposition testimony under Rule 30(b)(6) will not be longer than seven (7) hours. If a witness is presented in both an individual and Rule 30(b)(6) capacity, the parties will work together to determine a reasonable length for the deposition of that witness.

Inventor depositions:

2. Defendants' Proposal: Notwithstanding the foregoing, the Defendants may take a deposition of each inventor named on the patent-in-suit, whether it be pursuant to Rule 30(b)(1) or 30(b)(6), for up to ten (10) hours. Defendants' position is that if the cases are consolidated for pretrial purposes, Defendants will coordinate and limit each inventor deposition to 10 hours in total, rather than each Defendant taking its own deposition of each inventor.
3. Plaintiffs' Proposal: Plaintiffs are willing to discuss a reasonable length of any inventor deposition but Defendants have not yet made any showing or need to depart from the ordinary seven (7) hours limit under the Federal Rules of Civil Procedure.

Location of depositions:

4. Plaintiffs' Proposal: Reasonable location to be determined on a witness-by-witness basis.
5. Defendants' Proposal: Any party, named inventor, or representative (officer, director, or managing agent) of a party filing a civil action in this District Court must ordinarily be required, upon request, to submit to a deposition at a place designated within this District, or at another location in the United States convenient for the witness, subject to the ability of any foreign national to obtain visa approval for entry into the United States within the deposition period. Exceptions to this general rule may be made by order of the Court. All parties will make reasonable requests to their respective former non- U.S. employees to attend depositions in the United States.

Miscellaneous issues related to fact depositions that the parties agree on:

6. For any deposition conducted in a language other than English with use of an interpreter, each hour of testimony will be counted as one half hour for purposes of the limits described in Fed. R. Civ. P. 30.
7. The parties will discuss and work together in good faith concerning any requests to adjust the length of any particular deposition in excess of the limits described above. The parties each reserve their right to seek relief from the Court to limit the length of any particular deposition or take depositions in excess of the number and time limits described above.

8. For clarity, depositions of experts do not count against the limit on the number of depositions of fact witnesses.

iv. **Third-Party Subpoenas:** Any party which serves a subpoena upon a third party will simultaneously serve a copy of such subpoena upon every other party. Any party that receives documents from a third party pursuant to a subpoena will produce those documents to the other parties within ten (10) days. To the extent that third party subpoenas will reveal the identity of business partners for any party, the party serving the subpoena will mark the subpoena with the highest level of confidentiality under the protective order in this case when it is served on the other Defendants.

(c) **Electronically Stored Information:** The parties will meet and confer on electronic discovery and electronically stored information.

(d) **Protective Order:** The parties agree that a protective order will be necessary due to confidential business and financial information that will need to be exchanged in this action. The parties expect to present a stipulated protective order to the Court for its consideration.

(e) **Discovery Schedule:** The parties' proposed schedule for discovery and other dates are set forth in Exhibit A.

Defendants believe that an in-person Rule 16 Pretrial Scheduling Conference, scheduled at the Court's convenience, would be beneficial to the efficient resolution of these actions.

Plaintiffs believe that bifurcation of liability and damages is unnecessary, particularly in light of the fact that Defendants have pleaded an obviousness defense which presumably will include discovery and testimony related to commercial success. Plaintiffs see no reason to burden the Court or empanel a jury twice. Plaintiffs further believe that their jury demands are

proper because Plaintiffs are entitled to damages, including at least a reasonable royalty, for any infringement of the '775 patent, which is not limited to commercial sales but includes the use of the process in the U.S. or the import or offer to sale in the US of the product made using the infringing process.

Defendants request bifurcation of liability and damages discovery and trial and do not agree that the liability phase is an issue for a jury as there have been no product sales to create damages that would render Plaintiffs' jury demand applicable. It is Defendants' position that should a damages phase become necessary, the parties will jointly propose a schedule for any damages phase (including discovery and trial) within 30 days of any ruling on post-trial liability motions.

**9. Estimated Trial Length**

The parties estimate a five- to seven-day trial would be needed if all related actions filed in or transferred to this Court are consolidated for trial. It is Plaintiffs' position that this trial would cover both liability and damages. It is Defendants' position that this trial would cover only liability.

**10. Jury Trial**

None of the parties have waived their rights to a jury trial. Plaintiffs request a jury trial for every issue triable to a jury.

**11. Settlement**

There have not been settlement discussions to date.

**12. Related Proceedings**

Aside from the six '775 Patent Cases now pending in this Court, Teva has sued DRL and Amneal for infringement of the '775 patent in the following actions:

- *Teva Pharmaceuticals USA, Inc. v. Amneal Pharmaceuticals LLC*, No. 17-cv-416 (E.D.N.Y., filed Jan. 25, 2017) (stayed pending resolution of venue motions in D. Del.)
- *Teva Pharmaceuticals USA, Inc. v. Dr. Reddy's Labs, LTD.*, No. 17-cv-517 (D.N.J., filed Jan. 25, 2017)

As set forth above, Plaintiffs propose that in conjunction with consolidation for all purposes of the '775 Patent Cases now pending in this Court, Plaintiffs will agree to the transfer of C.A. No. 17-cv-517 from the District of New Jersey and C.A. No. 1:17-cv-416-JAM-AYS from the Eastern District of New York, to this District to be consolidated with these actions for all purposes. Amneal agrees that all '775 Patent Cases should be consolidated for pretrial purposes, but believes it is premature to order consolidation for trial at this time.

In addition, Teva previously sued Defendants DRL, Mylan, Synthon, Amneal, and Sandoz and Momenta in this court regarding four patents related to the now-dismissed '874 patent:<sup>7</sup> U.S. Patent Nos. 8,232,250 ("the '250 patent"), 8,399,413 ("the '413 patent"), 8,969,302 ("the '302 patent"), and 9,155,776 ("the '776 patent"). The cases were consolidated and a trial was held in September and October 2016. *See In re Copaxone Consolidated Cases*, No. 14-cv-1171 (D. Del., filed Sep. 10, 2014). On January 31, 2017, the Court found the four patents invalid. The Court's decision is currently on appeal to the United States Court of Appeals for the Federal Circuit. *See Teva Pharmaceuticals USA, Inc v. Sandoz Inc.*, No 17-1575 (Fed. Circ., docketed Feb. 6, 2017). *Inter partes* reviews of the '250, '413, and '302 patents were also instituted, and all claims of the '250, '413, and '302 patents were found to be unpatentable for obviousness. IPR2015-00643 ('250 patent); IPR2015-00644 ('413 patent); IPR2015-00830 ('302 patent). The P.T.A.B.'s decision is currently on appeal to the United

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<sup>7</sup> As noted above, the parties stipulated to, and the Court has ordered, a dismissal with prejudice of the '874 claims and counterclaims, subject to the terms set forth in Joint Stipulation and Order Dismissing with Prejudice Claims and Counterclaims Regarding U.S. Patent No. 9,402,874 (D.I. 72, 74).

States Court of Appeals for the Federal Circuit. *See Yeda Research and Development v. Mylan Pharmaceuticals Inc.*, No. 17-1594 (Fed. Circ., docketed Feb. 8, 2017). The appeals of this Court's decision and the P.T.A.B. decisions will be heard as companion cases by the same merits panel of the Court of Appeals.

Teva notes that these additional cases were Hatch-Waxman litigations and *inter partes* reviews involving the validity and/or infringement of several Orange Book patents, which claimed methods of treatment. They involved neither the '775 patent, nor any other patent claiming a process for manufacturing a composition of glatiramer acetate.

**13. Such other matters as counsel considered conducive to the just, speedy and inexpensive determination of this action.**

Teva seeks limited discovery from Mylan on an expedited basis to assess whether Teva will need to seek preliminary relief from the Court. On May 10, 2017 Mylan held its first quarter 2017 earnings conference call in which Mylan told investors that it has a June 2017 FDA target action date for ANDA No. 206936, and that it sees no barriers to approval and will be prepared to launch its proposed generic 40 mg glatiramer acetate product upon receiving approval. Based on these statements, Teva requested from Mylan a set of documents narrowly tailored to enable Teva to assess the need for a preliminary injunction. The Court should order Mylan to produce the requested documents in order to avoid the need for approaching the Court on an emergency basis should Mylan receive FDA approval of its ANDA in June 2017.

Mylan has agreed to produce a limited set of documents bearing on the relevant process steps claimed in the '775 patent on June 9, 2017. Therefore, there is no need for the Court to consider Plaintiffs' request for an order to produce documents. Moreover, Plaintiffs' document requests were not "narrowly tailored." To the contrary, they were drastically overbroad, unduly burdensome, and largely unrelated to the narrow process step claimed in the '775 patent. To the

extent Plaintiffs invoke the need for a preliminary injunction, Mylan's June 9, 2017 production will demonstrate that plaintiffs cannot show a likelihood of success on the merits of their infringement claim.

**14. Confirmation of Rule 26(f) Conference**

Counsel for the parties have conferred about each of the above matters.

Dated: June 5, 2017

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